

Customer No.: 07278

Docket No: 3940/0K188

Okay to enter S.H.
8/27/03 (S. Howard)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael Friedman et al.

Serial No.: 09/534,960

Art Unit: 1615

Confirmation No.: 3862

Filed: March 27, 2000

Examiner: S. Lee Howard

For: CONTROLLED DELIVERY SYSTEM OF ANTIFUNGAL AND KERATOLYTIC AGENTS FOR LOCAL TREATMENT OF FUNGAL INFECTIONS OF THE NAIL AND SURROUNDING TISSUES

INFORMAL COMMUNICATION

Please find the proposed claim amendments below:

47. (AMENDED) A sustained release therapeutic nail varnish composition comprising:

- (a) an antifungal effective amount of an antifungal agent;
- (b) a keratolytic agent in an amount sufficient to increase and facilitate penetration of said antifungal agent into the nail permeability of the nail;
- (c) greater than 3% (w/w) of a humectant to trap water;
- (d) water in an amount sufficient to hydrate the nail and thereby to further increase permeability of the nail in combination with said keratolytic agent;
- (e) a liquid nail lacquer component comprising a polymeric film forming agent and a volatile solvent, said agent selected to form a sustained release film upon application of said composition on a nail and evaporation of said volatile solvent; and
- (f) a volatile solvent;

said sustained release film configured to trap water from said composition and maintain it in contact with said nail, said water and said humectant in combination still further facilitating

penetration of said antifungal agent into the nail, and thereby enhancing therapeutic effectiveness of said antifungal agent.

96. (Amended) A sustained release therapeutic nail varnish composition comprising:

- (a) an antifungal effective amount of an antifungal agent;
- (b) a keratolytic agent in an amount sufficient to increase and facilitate penetration of said antifungal agent into the nail permeability of the nail;
- (c) a humectant to trap water;
- (d) a liquid nail lacquer component comprising a polymeric film forming agent and a volatile solvent; and
- (e) water; and
- (f) ~~a volatile solvent;~~

wherein upon application on a nail, the volatile solvent evaporates and a sustained release film coating forms on the surface of the nail, the sustained release film coating releasing the antifungal and keratolytic agents in respective effective amounts over a prolonged period of time and trapping water in contact with the nail; the humectant retaining water in the film; and said keratolytic agent and said water further increasing permeability of the nail surface and still further facilitating penetration of the released antifungal agent below the nail surface.

98. (Amended) A method of treating a fungal infection comprising administering to a subject a therapeutically effective amount of a sustained release therapeutic nail varnish composition, wherein the composition comprises:

- (a) an antifungal amount of an antifungal agent;
- (b) a keratolytic agent in an amount sufficient to increase and facilitate penetration of said antifungal agent into the nail permeability of the nail;
- (c) greater than 3% (w/w) of a humectant to trap water in a film;
- (d) water in an amount sufficient to hydrate the nail and thereby to increase permeability of the nail in combination with said keratolytic agent;
- (e) a liquid nail lacquer component comprising a polymeric film forming agent and a volatile solvent; and

Informal Communication

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~~(f) a volatile solvent;~~

said film forming agent being selected so as to form a sustained release film upon application of said composition on a nail of said subject and evaporation of said volatile solvent, said sustained release film configured to trap water from said composition and maintain it in contact with said nail, said water and said humectant in combination facilitating penetration of said antifungal agent into the nail, and thereby enhancing effectiveness of said antifungal agent.

We propose to cancel the following claims:

50, 51, 54, 55, 58, 59, 61, 62, 64, 65, 67, 68, 75, 84, 85, 86, and 94. Please note that we are keeping all independent claims, but will cancel these claims to simplify the issues.

Applicants' main points are as follows:

1. Friedman does not mention nails.
2. Skin is very different from nails in structure, composition and behavior. See Sun et al., 1997 Percutaneous Absorbtion Drugs Cosmetics Mechanisms, 3rd Ed. Marcel Dekker Inc.(NY), pp. 758-787, specifically page 760, lines 14-23; page 761, lines 1-5 and Tables 1 and 2; and page 763 lines 28-41 (highlighted in the email copy). This makes it inappropriate to (i) assume that Friedman applies to nails and (ii) apply teachings about how to treat skin to treatment of nails. The evidentiary reference is presented to show that Friedman cannot be combined willy nilly with Bohn.
3. Fungal infections of nails are tenacious and difficult to treat. While it may be considered as facilitating nail permeability, water is also recognized as promoting fungal growth. See evidentiary references MSN Medical Encyclopedia and Medline plus Medical Encyclopedia website information, of record (Response 12/17/02, Exhibits B and C respectively), especially MSN page 1, lines 11-30 and Medline page 2, lines 3-7 (highlighted in email copy). In the present claims water is not merely contacted with the nail for a

short period of time (until the varnish dries). Instead, it is trapped in a sustained release formulation and further retained therein by a humectant which would prevent its evaporation and prolong contact of water with the nail for a period of time substantially longer than any period of time that untrapped water would be present in contact with the nail in the Bohn formulation. It is therefore counterintuitive to include large amounts of humectant and water in a sustained release nail lacquer formulation.

Attached are PDF copies of all exhibits referred to herein.